Information Summary and Recommendations

Orthotics And Prosthetics Sunrise Review

November 1996

Washington State Department of Health

For more information or additional copies of this report contact:

Office of Health Services Development
PO Box 47851
Olympia, Washington 98504-7851

Phone: (360) 753-3234
Fax: (360) 664-0398

Bruce A. Miyahara
Secretary of Health

PREFACE

NOTE: The term "O&P provider" "O&P practitioner" or "O&Ps" will be used to substitute for "orthotist and prosthetist" throughout this report. These are accepted substitutions among these professionals.

The Sunrise Review Process

Legislative Intent

It is the Legislature's intent to permit all qualified individuals to enter a health care profession. If there is an overwhelming need for the state to protect the public, then entry may be restricted. Where such a need to restrict entry and protect the public is identified, the regulation adopted should be set at the least restrictive level.

The Sunrise Act, RCW 18.120.010, states that a health care profession should be regulated only when:

- Unregulated practice can clearly harm or endanger the health, safety or welfare of the public and the potential for harm is easily recognizable and not remote or dependent upon tenuous argument;
- The public can reasonably benefit from an assurance of initial and continuing professional ability; and
- The public cannot be protected by other more cost effective means.

After evaluating the criteria, if the legislature finds that it is necessary to regulate a health profession not previously regulated by law, the regulation should be consistent with the public interest and the least restrictive method. There are five types of regulation to be considered:

1. *Stricter civil actions and criminal prosecutions.* To be used when existing common law, statutory civil actions, and criminal prohibitions are not sufficient to eradicate existing harm.

2. *Inspection requirements.* A process enabling an appropriate state agency to enforce violations by injunctive relief in court, including, but not limited to, regulation of the business activity providing the service rather than the employees of the business when a service is being performed for individuals involving a hazard to the public health, safety, or welfare.

3. *Registration.* A process by which the state maintains an official roster of names and addresses of the practitioners in a given profession. The roster contains the location, nature and operation of the health care activity practiced and, if required, a description of the service provided. A registrant ~~could be~~ *is* subject to the Uniform Disciplinary Act, Chapter 18.130 RCW.

4. *Certification.* A voluntary process by which the state grants recognition to an individual who has met certain qualifications. Non-certified persons may perform the same tasks, but may not use "certified" in the title. A certified person is subject to the Uniform Disciplinary Act, Chapter 18.130 RCW.

5. *Licensure.* A method of regulation by which the state grants permission to engage in a health care profession only to persons who meet predetermined qualifications. Licensure protects the scope of practice and the title. A licensee is subject to the Uniform Disciplinary Act, Chapter 18.130 RCW.

Overview of Proceedings

The Department of Health notified the applicant group, all professional associations, board and committee chairs, and staff of the Sunrise Review. Meetings and discussions were held and documents circulated to all interested parties.

Regulatory agencies in all other states were requested to provide sunrise reviews, regulatory standards, or other information which would be useful in evaluating the proposal. A literature review was conducted. Staff have reviewed all submitted information and asked for feedback from interested parties.

An initial public meeting was held on June 3, 1996, to identify the relevant issues and key players. A public hearing was conducted on August 28, 1996. The hearing panel included staff from the Department of Health and a public member. Interested persons were allowed to give presentations. There was an additional ten-day written comment period.

Following the public hearing and additional written comments, a recommendation was made based on all information received and in consultation with the public hearing panel. The proposed final draft was reviewed and approved by the Health Systems Quality Assurance Assistant Secretary and the Department Secretary. The final report was transmitted to the Legislature via the Office of Financial Management.

EXECUTIVE SUMMARY

There is no direct regulation of O&P providers in the state of Washington. Orthotists design, make, and fit braces and other supportive devices for patients who have an injury or disease that interferes with normal body functions. Prosthetists make artificial limbs for patients who have lost their own from injury or disease. Occupational Therapists may provide "selected" orthotic and prosthetic devices.

Major technological advances have made this service an invaluable part of the health care delivery system.

In January, 1996, HB 2407 was forwarded to the Department of Health for sunrise review. The legislation calls for licensing of O&P providers by the department, with the advice of an Advisory Committee.

Findings:

1. A large number of members of the public participated in this review, and even more were prepared to. This is a clear indication, unlike many other sunrise reviews, of the level of public demand.

2. Orthotics and prosthetics are important elements of the health care system. Orthotists provide braces to persons with injuries or illnesses that impede their movement and daily functioning. Prosthetists provide artificial limbs to help amputees or persons born without a limb or limbs.

3. O&P providers often work in teams with physicians, Occupational Therapists (OTs), Physical Therapists (PTs), and physicians to provide initial care to patients. On-going care is usually carried out solely by O&Ps. Occupational therapists have a scope of practice that allows them to make "selected" O&P devices.

4. Patients are usually referred by physicians, sometimes by PTs or OTs. Some patients told the review panel that they had a bad experience with the physician or surgeon and sought out, on their own initiative, an O&P.

5. Although there is no legal requirement for a prescription, O&P providers require a prescription from a physician, osteopathic physician, chiropractic physician, naturopathic physician, podiatric physician, advanced registered nurse practitioner, or dentist.

6. The level of training required, as exemplified by the University of Washington's program, seems adequate for the type of work being done. Evidence is lacking that persons holding private certification as prosthetists or orthotists are not properly trained.

7. The potential for economic harm exists from unregulated practice due to the history of fraudulent practice.

8. The applicant also presented instances of sexual abuse. Most patients for these services have gone through a traumatic event or are dealing with a devastating disease, and therefore in a vulnerable position from a psychological viewpoint.

9. Evidence was presented that some persons presenting themselves as O&P providers may deliver sub-standard care. Improper care causes three types of economic harm. First, resources are wasted on unneeded or inappropriate prosthetic or orthotic devices. Second, patients are out of work or otherwise not functioning members of society for extended periods of time. Third, the patient suffers psychologically from the failure to receive proper care.

10. The extent (in terms of numbers of cases, for example) to which sub-standard care is being provided is not clear. Therefore, while regulating O&P providers would improve public health, the specific amount of that improvement is not empirically known.

11. Testimony was presented that some O&P providers are not sensitive to the needs of recent amputees and other patients and handle them inappropriately. However, it is unlikely that any legislation can regulate provider sensitivity.

12. There is a perception among the public that not licensing O&P providers implies that amputees and other patients are of less value than patients or clients of other professionals who are licensed, including cosmetologists and veterinary assistants.

Recommendations:

The review panel considered several options prior to making its recommendation to the Secretary. These included:

- Doing nothing beyond the current practice of self-regulation,
- Registration of O&P providers; or
- Licensure of O&P providers, both with and without exemptions for other health care practitioners.

1. The applicant's proposal, with some major modifications to make implementation of the statute possible, should be adopted, regulating Orthotists and Prosthetists at the level of licensure, and as two individual professions. (NOTE: an improved version of the bill has been developed but was not officially transmitted to the department prior to the publication of this report.) O&P Assistants and Aides should not be included in the regulation. Advanced Registered Nurse Practitioners should be included in the definition of "authorized health care practitioner" for the purposes of prescribing O&P devices.

1A. There should not be a traditional "grandfather" provision. However, the proposed concept of allowing license applicants to substitute some experience for some education requirements is a sound one.

2. Occupational Therapists should be allowed to continue to have their authority to make "selected" devices. This will require a specific exemption clause, limiting Occupational Therapists to their current scope. An OT wishing to provide the full range of O&P services would need to become licensed. However, the department should be given specific rule making authority to establish a process by which the selections are made.

3. The advisory committee should review and monitor the exemptions proposed for types of devices, and recommend to the Secretary any statutory changes that may be needed to properly protect the public.

CURRENT REGULATION AND PRACTICE

There is no direct regulation of O&P providers in the state of Washington. A national private certification process exists. Approximately 80 people have private certification either as an Orthotist, Prosthetist, or both.

Orthotists design, make, and fit braces and other supportive devices for patients who have an injury or disease that interferes with normal body functions. Prosthetists make artificial limbs for patients who have lost their own from injury or disease. The educational background for each profession is similar, but it is possible to be one type of professional without being the other type. Major technological advances have made this health care service an invaluable part of the delivery system. Physicians and other providers no longer expect to keep up with these advances and rely on O&P providers.

There have been cases of fraud involving O&P providers. Those cases have been handled in the court system, often initiated by the state's Department of Labor and Industries or Department of Social and Health Services.

Occupational Therapists may design, fabricate, or apply "selected orthotic and prosthetic devices or selected adaptive equipment" under RCW 18.59.020(2).

The State of New Jersey is the only state that currently has regulation of O&P practitioners. The law was passed nearly four years ago, and rules are still being developed. This delay apparently was caused by budget problems, not policy concerns.

Proposal for Sunrise Review

In January, 1996, HB 2407 was forwarded to the Department of Health for sunrise review. The legislation calls for licensing of O&P providers by the department, with the advice of an Advisory Committee. Orthotists and Prosthetists are defined, as is the practice. Exemptions are made for those making or fitting other than custom-made devices for long-term use, such as braces used after surgery, hand splints, etc. Training requirements are specified. The bill contains an emergency clause.

Flexibility is given to the advisory committee in recommending initial licensure to those persons who have at least five years of experience but not necessarily the full education requirements otherwise needed. This is intended to allow some persons to be licensed who are currently practicing who have worked well in the field, especially in specialty areas, and who may not otherwise qualify for licensing. It is not strictly a "grandfather" clause in that it is permissive in allowing a substitution of experience for education, rather than outright exemption from licensure requirements. It is estimated that there about eight persons in this state who would be potentially subject to this provision.

Initial Public Meeting

An initial public meeting was held on June 10, 1996, and attended by interested parties. The purpose of this meeting was to identify key stakeholders and valid issues. The applicant representatives explained their profession, the contents of the bill, and answered questions.

INFORMATION SUMMARY

Department staff and the hearing panel reviewed all documents received during the review process. In this "Summary of Information" section, the text is paraphrased or quoted by the department from all documentation received and audio tape that was recorded at the public hearing. It does not reflect the department's findings, which are found in a later section of this report. Complete documentation of these viewpoints is in the department's files and is disclosable to the public upon request.

Washington Orthotics and Prosthetics Association, said "Consumers of orthotic- prosthetic care in Washington state are presently exposed to actual and potential harm in the following ways."

"(1) Physical Harm: orthoses and prostheses fit intimately on the human body. Improper fit due to inadequate education and training of the patient or the lack of sufficient follow-up care by the practitioner can result in the device, rather than improving the patient's life, actually complicating it and increasing risk to the person....a poorly designed orthosis or prosthesis can... be a weapon, causing further medical complications and result in serious physical injury to the patient....."

"(2) Psychological harm: the physically challenged individual or his loved ones, when presented with an inadequate device or incompetent service, can and do experience emotional harm in the following ways: decreased self-confidence; diminished self-worth; distress from chronic discomfort resulting from improper fit or design of the device; sexual harassment or embarrassment due to partial or complete disrobing for given fitting procedures; increased self-consciousness due to an improper or ill-fitting device negatively impacting gait; diminished realization of the patient's potential function; and the consumer's sense of being overwhelmed by odds in a society that fails to protect him/her from serious physical injury....."

"(3) Financial harm: because orthotic and prosthetic practice is unregulated, consumers, their loved ones and the taxpayers of this state suffer economic harm in the following ways: decreased productivity and function and added dependence; recidivism, significant financial cost incurred if care not only fails to restore function but produces further complications; fraud, through improper billing by untrained providers and promulgated abuse by trained providers who bill for services not performed or for services whose costs far exceed accepted ethical and mandated limits....."

"Licensure cannot prevent harm to the public. Rather, it offers assurance to the public of initial and continuing professional ability of O&P practitioners. By requiring minimum competency to provide custom-made orthoses and prostheses, the likelihood of harm by poorly designed devices is reduced."

"With licensure, patients and their families have a state regulatory mechanism for recourse for lodging complaints to a disciplining authority when they are subjected to unprofessional conduct. In the absence of regulation, untrained or unscrupulous providers treating the physically challenged of Washington state, are immune from such a disciplining authority and lack the accountability that the public health, safety and welfare requires."

Dr. Nancy Worsham indicated that she selects an O&P provider who is certified (nationally) and with whom she has worked in the past. It should be noted that the psychological harm the applicants refer to interferes with clear patient decisionmaking. This makes it more important that the state provide protection.

Jan Thompson provided a video tape showing the effects of improper design and fitting of devices.

Jeannie Gorman, attorney and O&P patient, said "I am a civil rights attorney practicing in Seattle. I contracted polio at the age of two and have worn a custom orthotic for close to 30 years. The custom orthotic (brace) is my freedom. Without it I am unable to walk. ...I have been self-referred to orthotists for as long as I can remember. My orthopedic surgeons have rarely been able to refer me to an orthotist. ...The most critical elements of my relationship with any orthotist is trust and confidence. The orthotist is much more than merely a technician; he must determine the specific and specialized needs of the patient."

"I have seen the orthotics profession and materials at their disposal change and become quite complicated. I benefit from lightweight carbon fibers and aerospace pioneered titanium and other strong, lightweight materials...."

"Four months ago, in an attempt to find a cheap orthotist (my insurance, the Basic Health Plan, does not cover orthotics), I visited a new orthotist. I went to him every day for over a week but he was unable to correct the problem I was having. In frustration, he told me that he didn't know what else to do and fashioned a 'quick fix' that made my brace fail even when I was in his office, a fact of which he was aware. I walked ten feet out of his office, my brace failed, I fell and I broke my arm. I believe that the 'quick fix' he fashioned fell far below the standard of care...my only recourse is through the courts and the tort system. As an attorney I am well aware of how expensive a lawsuit is. I am also aware that our courts are stretched to the limit. Judicial efficiency is simply not served when litigation is the only answer to this issue."

"...if there are any other consumer patients out there who suffered a serious injury like mine at the hands of this unqualified orthotist whom I visited in April, over time he will lose his license to practice. Without licensure, he simply continues to cause harm to his patients."

"[re: grandfather clause] I believe that five years of experience is not enough to permit the grandfathering in of current practitioners. Patients deserve to know that their orthotist is qualified. Even an orthotist who has been practicing for 30 years should be required to pass some baseline competency exam."

Myrtle Schenerwerk provided a personal account of how she was subject to physical and emotional harm at the hands of an untrained provider.

Winslow Granlund brought with him the background of being a former state senator. He said that there should not be a blanket "grandfather" position, but there should be an examination or education and standards met to become licensed. These providers have a great impact on the health of our citizens, yet it is harder for trench diggers to get permission to work.

Florence Jewell emphasized that practitioners should have to prove they have proper training and education.

Dee Malchow testified that she works at Harborview Medical Center as a nurse and is herself an amputee. She stressed the psycho-social issues. The attitude and approach of the O&P practitioner has a direct bearing on the patient's well-being and sense of self-worth. Basic education of practitioners in how to treat the special needs of these patients would help alleviate the problem. At Haborview, they encourage a team approach to the provision of care.

Dr. Frank Tubridy indicated that as a physician and parent of a patient, he realizes the importance of having competent O&P providers. He relies on them to give his patients the devices and services they need.

Becky Byxbe provided a personal account of a serious accident and problems with obtaining proper O&P care for several years. She highlighted the serious psychological problems in dealing with new amputation. "We count on the state to protect us."

Dr. Eric Bowden emphasized the complex and independent nature of O&P work. Licensure will provide a standardized level of care.

Carl Nelson, WSMA, indicated that physicians he has talked to agree that some level of regulation is needed in order to provide Uniform Disciplinary Act protection. However, they felt the level of licensing was not justified under the sunrise criteria. In addition, he pointed out that there were numerous technical problems with the draft legislation, and felt a "grandfather" provision was not needed. He raised the question as to whether there was an impact on the "any willing provider" statute.

Evenlyn McDonald, RN and patient, said "As a nurse, who is also handicapped, I am writing to voice my support for the Washington State Orthotics Prosthetics Licensure initiative."

"I had polio as a child and have worn a long leg brace since the age of two. At a point in my pre-teens, a brace was made that did not have a proper fit. It resulted in my leg developing an abnormal angle. The lower part of the leg is not straight down from the knee but angels outward. This could have been avoided with a brace that was properly fit. I'm not sure licensure would eliminate this but at least there would be a course of action one could take."

"...Once, when I was lecturing in a small town, my brace broke. Since I was going to be there another week I went to the local brace company and was promptly told I needed several hundreds of dollars of repair done. What they wanted to do didn't seem logical to me, so I declined to have any work done. For the rest of the week I struggled with crutches. When I returned home, my local brace company replaced one piece of metal for about $40. I was angry for I knew that first brace company felt like they could take advantage of me since I was in an emergency situation...."

"...licensure sets a standard and ethical guidelines. In addition, it allows me, the client, to know who has the basic skills. Would you want an unlicensed nurse caring for you?"

Patty Bates discussed how O&P is a very sophisticated field. She supports the licensure approach. She noted that the work of O&Ps, PTs, and OTs overlapped. She hopes that regulation of O&P's does not mean that PTs and OTs would be prevented from continuing current practices.

Sylvia Kauffman, Washington State Occupational Therapists Association, noted that OTs mostly deal with upper extremity amputees. The association supports licensing of O&P providers, but noted that OTs need an exemption to be allowed to continue the practice they currently are allowed to do.

Blayne Myhre is a pharmacist and orthotist specializing in orthopedic devices. He believes that a "grandfather" provision should be allowed for those who have BOC or other national certification, plus some experience. He believes this would allow them to have a "limited scope of practice."

DSHS, said "Currently there are no state regulations covering prosthetic and orthotic providers. Therefore the only item that is required by medical Assistance Administration (MAA) is our provider number, which allows them to bill Medicaid for covered services. This allows the potential of our clients to receive prosthetics and orthotics that do not meet their medical needs and could even cause their condition to become worse. The providers could also be submitting fraudulent requests to our department."

"We feel some kind of regulation that would require a level of education of the prosthetist or orthotist, such as a Bachelor's degree...and/or that they meet the requirements of the American Board Certification, would be helpful to DSHS in ensuring our clients' medical needs are served in the most effective manner available."

FINDINGS

1. A large number of members of the public participated in this review, and even more were prepared to. This is a clear indication, unlike many other sunrise reviews, of the level of public demand.

2. Orthotics and prosthetics are important elements of the health care system. Orthotists provide braces to persons with injuries or illnesses that impede their movement and daily functioning. Prosthetists provide artificial limbs to help amputees or persons born without a limb or limbs. Some practitioners are both orthotists and prosthetists. From the days of crudely crafted wooden legs, these professions have developed into sophisticated, engineering based providers of materials that are essential to many people.

3. O&P providers often work in teams with physicians, OTs, PTs, and physicians to provide initial care to patients. On-going care is usually carried out solely by O&Ps. Occupational therapists (OTs) have a scope of practice that allows them to make "selected" O&P devices.

However, the process of selection and any list of selected devices does not exist in statute or in rules.

4. Patients are usually referred by physicians, sometimes by PTs or OTs. Some patients go to O&Ps directly, subject to insurance company (or other payer) restrictions. Some patients told the review panel that they had a bad experience with the physician or surgeon and sought out, on their own initiative, an O&P.

5. Although there is no legal requirement for a prescription, O&P providers require a prescription from a physician, osteopathic physician, chiropractic physician, naturopathic physician, podiatric physician, advanced registered nurse practitioner, or dentist.

6. The level of training required, as exemplified by the University of Washington's program, seems adequate for the type of work being done. The national certification program also maintains strict standards of education, continuing education, and proper experience. Evidence is lacking that persons holding private certification as prosthetists or orthotists are not properly trained.

7. The potential for economic harm exists from unregulated practice due to the history of fraudulent practice. The applicant presented information detailing fraudulent behavior (and court judgement) of one practitioner who nonetheless continues to offer O&P services.

8. The applicant also presented instances of sexual abuse. Most patients for these services have gone through a traumatic event or are dealing with a devastating disease, and therefore in a vulnerable position from a psychological viewpoint.

9. Evidence was presented that some persons presenting themselves as O&P providers may deliver sub-standard care. And improper care causes three types of economic harm. First, resources are wasted on unneeded or inappropriate prosthetic or orthotic devices. Second, patients are out of work or otherwise not functioning members of society for extended periods of time. Third, the patient suffers psychologically from the failure to receive proper care.

10. The extent (in terms of numbers of cases, for example) to which sub-standard care is being provided is not clear. Furthermore, prosthetic and/or orthotic devices sometimes fail even when provided by properly trained and nationally certified providers. Regulation of the profession would not eliminate or even reduce the proportion of the problems arising from normal failure. Therefore, while regulating O&P providers would improve public health, the specific amount of that improvement is not empirically known.

11. Testimony was presented that some O&P providers are not sensitive to the needs of recent amputees and other patients and handle them inappropriately. However, it is unlikely that any legislation can regulate provider sensitivity. Most university O&P training programs do require coursework in psychological and ethical behavior.

12. Finally, there is a perception among the public that not licensing O&P providers implies that amputees and other patients are of less value than patients or clients of other professionals who are licensed, including cosmetologists and veterinary assistants.

RECOMMENDATIONS

Options Considered

The review panel considered several options prior to making its recommendation to the Secretary. These included:

- Doing nothing beyond the current practice of self-regulation.
- Registration of O&P providers.
- Licensure of O&P providers, both with and without exemptions for other health care practitioners.

1. The applicant's proposal, with some major modifications to make implementation of the statute possible, should be adopted, regulating Orthotists and Prosthetists at the level of licensure, and as two individual professions. (NOTE: an improved version of the bill has been developed but was not officially submitted to the department prior to the publication of this report.) O&P Assistants and Aides should not be included in the regulation. Advanced Registered Nurse Practitioners should be included in the definition of "authorized health care practitioner" for the purposes of prescribing O&P devices.

Rationale:

- Sufficient psychological, physical, and economic harm to the public is occurring from the unregulated practice of orthotists and prosthetists.

- Patients of O&Ps should be protected to the same extent that other recipients of significant health care services are. No mechanism exists to protect these patients because those who provide sub-standard care cannot obtain and maintain national certification. There seems to be a sufficient number of these sub-standard providers who have created, at the very least, a significant potential for serious harm to the public.

- While many people practice in both fields, one field is not an "add on" to the other, making it necessary to have two license categories.

- The applicant's version of the legislation is technically flawed, with the advisory committee given powers it cannot have (by definition). It is possible to rewrite these sections, drop others that are not needed due to standard authority already granted to the department, and make other "clean up" changes. The emergency clause should be eliminated to allow sufficient time to start up a licensing program. Powers and duties between the department and the advisory committee need to be clarified. No need to regulate assistants or aides was shown. Advanced Registered Nurse Practitioners (ARNPs) should be allowed to continue to prescribe and otherwise deal with O&P patients.

1A. There should not be a traditional "grandfather" provision. However, the proposed concept of allowing license applicants to substitute some experience for some education requirements is a sound one.

Rationale:

- There is sufficient harm and potential harm to justify licensure. A "grandfather" provision as traditionally defined would allow anyone calling themselves an O&P provider to become licensed, without qualification. This approach cannot be justified due to the level of harm.

- The idea of allowing some experience to substitute for some education requirements will help those qualified providers, especially those who have specialized, to become licensed in a sound manner. There are apparently only a handful of providers who could take advantage of this provision.

- The advisory committee can evaluate these applications and recommend to the Secretary appropriate action.

2. Occupational Therapists should be allowed to continue to have their authority to make "selected" devices. This will require a specific exemption clause, limiting Occupational Therapists to their current scope. An OT wishing to provide the full range of O&P services would need to become licensed. However, the department should be given specific rule making authority to establish a process by which the selections are made.

Wording could be as follows:

"Occupational Therapists regulated under RCW 18.59 may only practice orthotics and prosthetics, as defined in this act, to the extent allowed by their scope of practice."

Added to RCW 18.59.130: "(3) The Board shall develop rules to establish a process by which the orthotic and prosthetic devices made by occupational therapists, as defined in RCW 18.59.020(2), are selected."

Rationale:

- OTs provide limited O&P services, primarily in the context of helping patients become functional again. These devices are usually for upper extremities of the body.

- Confusion exists as to who makes "selections" and why. While there is no indication that the current process of case-by-case determination, using national standards from the profession itself, is causing harm, with the new regulation of O&P providers, the issue needs to be clarified.

3. The advisory committee should review and monitor the exemptions proposed for types of devices, and recommend to the Secretary any statutory changes that may be needed to properly protect the public.

Rationale:

- No evidence was provided to support the inclusion of the exemptions as proposed. However, there was also no evidence there should not be any such exemptions. Having a professional group, such as the advisory committee, keep an eye on things will help assure these exemptions are indeed appropriate.

REBUTTAL STATEMENTS

An addition to this year's sunrise review process was a "rebuttal" period. During this time, participants could provide the department with a 300 word (maximum) statement for each recommendation with which they disagreed.

Washington State Medical Association Rebuttal:

The quote should not say that the physicians I talked to agree that some level of regulation is needed. The more correct statement would be that further regulation is not necessary. And while some regulation might be appropriate at some time, we oppose this legislation.

In addition, we believe that the proponent failed to demonstrate "overwhelming need" for the regulation and that they fail to meet the sunrise criteria.

PARTICIPANT LIST

Albert, David *State Board of Health*
Ambur, Richard *Washington Orthopedic Association*
Bates, Patty *citizen*
Bertrand, Ken *Group Health Cooperative*
Bielinski, Lori *American Massage Therapy Association*
Bogard, Becky *Washington State Physical Therapy Association*
Boldt, Jim *Washington State Hospital Association*
Bonton, Eric *citizen*
Broderick, Dave *Washington State Hospital Association*
Byxbe, Becky *citizen*
Campbell, Redge *Washington Occupational Therapy Association*
Carlson, Ted *citizen*
DeFord, Richard *citizen*
Eddinger, Len *Washington State Medical Association*
Entenmann, Karl *Washington Orthotic & Prosthetic Association*
Federici, Nick *Washington State Nurses Association*
Gjurasic, Mark *Washington Orthotic & Prosthetic Association*
Gorman, Jeannie *citizen*
Granlund, Win *citizen*
Grant, Linda *lobbyist*
Hewey, Bernard *Washington Orthotic & Prosthetic Association*
Hoffmeister, R. *citizen*
Hoyles, Carolyn *citizen*
Iher, Kathy *citizen*
Jewett, Florence *citizen*
Johnson, Julie *Legislative Committee*
Kauffman, Sylvia *Washington Occupational Therapy Association*
Lindstrom, Steve *Acupuncture Association of Washington*
Malchow, Dee *Harborview Medical Center*
Mc Rae, Jack *Blue Cross*
McDonald, Evy *citizen*
McGaffick, Gail *lobbyist*
McNamara, Dan *citizen*
Menzies, Ellie *Hospital & Healthcare Employees Union*
Merten, Lis *Washington Retail Association*
Miller, Robert *Department of Health*
Mktrichian, Emanual *GHC Tacoma Speciality Center*
Myhre, Blayne *White Cross Orthopedic*
Nelson, Carl *Washington State Medical Association*
Osborne, David *citizen*
Paxton, Jan *The Valley Clinic*
Plack, Scott *Group Health Cooperative of Puget Sound*

Representative Eileen Cody
Robertson, Arlene *Department of Health*
Sandison, Trevor *Free Standing Ambulatory Surgical Centers*
Scanlin, Susan *Federal Way Foot & Ankle Clinic*
Schenework, Betty *citizen*
Shafer, Keith *Department of Health*
Simons, Ann *lobbyist*
Sorenson, Mel *National Associaiton of Independent Insurers*
Teeter, Beverly *Department of Health*
Teubner, Diane *citizen*
Thatcher, Lisa *lobbyist*
Thurman, Duane *Washington State Healthcare Policy Board*
Tubridy, Frank *citizen*
Van DenBroek, Patty *Washington Orthotic & Prosthetic Association*
Varnau, David *Washington Orthotic & Prosthetic Association*
Wagner, Ron *lobbyist*
Walgren, Gordon *Washington State Pharmacy Association*
Washington Association of Physician Assistants
Washington State Medical Center
Weaver, Ron *Department of Health*
Webster, Cliff *Washington Association of Health Underwriters*
Wehrly, Steve *citizen*
Wendt, Rick *citizen*
White, Jackie *lobbyist*
Wickman, Rick *Blue Cross*
Williams, Brian *Washington Orthotic & Prosthetic Association*
Williams, Don *Department of Health*
Worshan, Nancy *citizen*
Wright, James *citizen*
Yamane, Ann *Washington Orthotic & Prosthetic Association*

REVIEW PANEL

Callie Wilson
Office of Community and Rural Health
Department of Health

Nicholas Garcia
Office of Legislative and Constituent Affairs
Department of Health

Stephen Boruchowitz
Health Systems Quality Assurance
Department of Health

Wilma Van Buren
Public member

LITERATURE REVIEW

Cobb, J.W. Models for delivery of prosthetic services to geriatric patients. Top Geriatric Rehabilitation 1992; 8(1): 59-63.

Wong J., Wong S., Noble T., Yabsley R.H. Effects of an experimental program on post-hospital adjustment of early discharged patients. International Journal of Nursing Study 1990; 27(1): 7-20.

Federal Registry. Medical devices; illustrative and designated lists for device tracking -FDA. 1993 August 16;58(156):43451-5.

Clarke J., Walmsley A., McLaughlin E., Bradnock G. Postgraduate prosthetic training within the community dental service. Community Dental Health; 1992(9): 393-7.

Pringle, R.G. Halo vs. Minerva-- which orthosis? Paraplegia 1990 June; 28(5):281-4.

Mishra N., Yahiro M., Morrey B. The food and drug administration regulation of orthopedic devices. The Journal of Bone and Joint Surgery 1994 June; 76(6): 919-922.

APPENDIX A

HOUSE BILL 2407

H-3663.5

HOUSE BILL 2407

State of Washington 54th Legislature 1996 Regular Session

By Representatives Dyer, Cody, Dickerson, Tokuda, Murray, Mason and Costa

Read first time 01/10/96. Referred to Committee on Health Care.

AN ACT Relating to orthotic-prosthetic services; adding a new chapter to Title 18 RCW; creating a new section; and declaring an emergency.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF WASHINGTON:

NEW SECTION. **Sec. 1.** It is the intent of the legislature that sections 2 through 23 of this act accomplish the following: Safeguard public health, safety, and welfare; protect the public from being mislead by unethical, ill-prepared, unscrupulous, and unauthorized persons; assure the highest degree of professional conduct on the part of orthotists and prosthetists as well as orthotic and prosthetic assistants; and assure the availability of orthotic-prosthetic services of high quality to persons in need of the services. It is the purpose of sections 2 through 23 of this act to provide for the regulation of persons offering orthotic-prosthetic services to the public.

NEW SECTION. **Sec. 2.** Unless the context clearly requires otherwise, the definitions in this section apply throughout this chapter.

(1) "Advisory committee" means orthotics and prosthetics advisory committee.

(2) "Department" means department of health.

(3) "Person" means an individual, partnership, an unincorporated organization, or corporate body, except that only an individual may be licensed under this chapter.

(4) "Secretary" means secretary of health.

(5) "Orthotics" means the science and practice of evaluating, measuring, designing, fabricating, assembling, fitting, adjusting, or servicing, as well as providing the initial training necessary to accomplish the fitting of an orthosis for the support, correction, or alleviation of neuromuscular or musculoskeletal dysfunction, disease, injury, or deformity. The practice of orthotics encompasses evaluation, treatment, and consultation.

Among classes of orthoses, there exist three major types:

(a) Custom-fabricated, also known as custom-made;

(b) Prefabricated, also known as custom-fitted, or as off-the-shelf; and

(c) Direct formed, also known as direct molded.

Using a body of knowledge from biomechanics, pathomechanics, material science, and specialized manufacturing processes, the orthotist uses levers, three-point force systems, hydrostatics, joint axis alignment, and axial loading techniques to achieve the goals of improving both static and dynamic balance as well as stability. As a science, orthotics includes the application of static and dynamic forces to the human frame in pressure tolerant areas and minimization of those forces in pressure intolerant areas. With basic postural and gait analysis, orthotists assess and design orthoses to maximize function, and provide not only the support but the alignment necessary in the sagittal, transverse, and coronal planes to either prevent or correct deformity or to improve the safety and efficiency of mobility or locomotion, or both. The practice of orthotics includes providing continuing patient care in order to assure proper fit and function of the orthotic device by periodic evaluation.

(6) "Orthotist" means a person licensed to practice orthotics under this chapter. An orthotist evaluates, measures, designs, fabricates, fits, services, and provides the initial training necessary to accomplish the fitting of orthoses that use static and dynamic forces

for the support or correction of disabilities caused by neuro-musculoskeletal diseases, injuries, or deformities.

(7) "Orthotic assistant" means a person licensed to assist in the practice of orthotics under the supervision or with the regular consultation of a licensed orthotist.

(8) "Orthotic aide" means a person who is trained to perform specific orthotic techniques under professional supervision as defined by the advisory committee but who does not perform activities that require advanced training in the sciences or practices involved in the profession of orthotics.

(9) "Orthosis" means a custom-fabricated, definitive brace or support that is designed for long-term use. "Orthosis" does not include the following assistive technology devices: Commercially available knee orthoses used following injury or surgery; spastic muscle tone-inhibiting orthoses; upper extremity adaptive equipment; finger splints; hand splints; face masks used following burns; wheelchair seating that is an integral part of the wheelchair and not worn by the patient; fabric or elastic supports; corsets; arch supports; low temperature-formed plastic splints; trusses; elastic hose; canes; crutches; cervical collars; dental appliances; or other similar devices commonly carried in stock by a pharmacy, department store, corset shop, or surgical supply facility.

(10) "Prosthetics" means the science and practice of evaluating, measuring, designing, fabricating, assembling, fitting, adjusting, or servicing as well as providing the initial training necessary to accomplish the fitting of a prosthesis through the replacement of external parts of a human body lost due to amputation or congenital deformities or absences. As a science, prosthetics includes the application of static and dynamic forces to human tissues in pressure-tolerant areas and minimization of pressures in pressure-intolerant areas. The practice of prosthetics also includes the generation of an image, form, or mold that replicates the patient's body or body segment and that requires rectification of dimensions, contours, and volumes for use in the design and fabrication of a socket to accept a residual anatomic limb to, in turn, create an artificial appendage that is designed to support either body weight or improve or restore function or cosmesis, or both. Involved in the practice of prosthetics is the clinical assessment of the requirements necessary for the most efficient center of gravity pathway using a knowledge of moments and

torque to accomplish optimum alignment of joint axes and weightbearing load lines for safety and efficient function. The practice of prosthetics includes providing continuing patient care in order to assure proper fit and function of the prosthetic device by periodic evaluation.

(11) "Prosthetist" means a person who is licensed to evaluate, measure, design, fabricate, fit, and service as well as provide the initial training necessary to accomplish the fitting of prostheses to either improve or restore function or cosmesis, or both, through the replacement of external parts of the human body due to amputation or congenital deformities or absences.

(12) "Prosthetic assistant" means a person licensed to assist in the practice of prosthetics under the supervision or with the regular consultation of a licensed prosthetist.

(13) "Prosthetic aide" means a person who is trained to perform specific prosthetic techniques under professional supervision as defined by the advisory committee, but who does not perform activities that require advanced training in the sciences or practices that are involved in the profession of prosthetics.

(14) "Prosthesis" means a definitive artificial limb that is alignable, or articulated, or, in lower extremity applications, capable of weightbearing. "Prosthesis" means an artificial medical device that is not surgically implanted and that is used to replace a missing limb, appendage, or other external human body part including an artificial limb, hand, or foot. The term does not include artificial eyes, ears, fingers or toes, dental appliances, ostomy products, cosmetic devices such as artificial breasts, eyelashes, or wigs, or other devices that do not have a significant impact on the musculoskeletal functions of the body. In the lower extremity of the body, the term "prosthesis" does not include prostheses required for amputations distal to and including the transmetatarsal level. In the upper extremity of the body, the term "prosthesis" does not include prostheses that are provided to restore function for amputations distal to and including the carpal level.

(15) "Definitive" means a class of orthoses-prostheses that are durable in nature, whose design is appropriate for the duration of medical need.

(16) "Custom-made" means the design and fabrication from raw materials of a device for a specific patient and requires the

generation of an image, form, or mold that replicates the patient's body or body segment, and, in turn, involves the rectification of dimensions, contours, and volumes to achieve proper fit, comfort, and function for that specific patient.

(17) "Temporary" means for a period of no more than six months with no repeats.

(18) "Short term" means designed or intended for a temporary, interim period of treatment, characterized usually by the early phase or initial treatment of disability, injury, or recovery, and generally fabricated of less-durable materials and does not apply to definitive orthoses or prostheses.

(19) "Long term" means designed or intended for use for the period of injury, disability, or recovery until the orthosis-prosthesis becomes unusable due to wear or patient body change.

(20) "Direct-formed" means a process of fabricating a device made of materials, usually of low-temperature moldability, so that it can be formed or shaped during the molding process directly on the patient's body or body segment without risk of injury to the patient's tissues.

(21) "Low temperature" means moldable or formable below one hundred sixty degrees Fahrenheit.

(22) "Prefabricated" means manufactured as a commercially available stock item for no specific patient. The fitting of prefabricated devices does not involve a separate interim process of generating an image form, or mold that replicates that specific patient's body or body segment and does not require the design and fabrication of the device from raw materials for that specific patient; the fitting of prefabricated devices involves only the adjustment or custom-fitting, to the extent possible, of commercially available off-the-shelf devices to treat patients' biomechanical and medical needs.

(23) "Authorized health care practitioner" means licensed physicians, osteopathic physicians, chiropractors, naturopaths, podiatric physicians and surgeons, and dentists. However, nothing in this section alters the scope of practice of these practitioners as defined in their licensure laws.

NEW SECTION. **Sec. 3.** Notwithstanding the provisions of chapter 18.130 RCW, a consultation and periodic review by an authorized health care practitioner is not required for evaluation, repair, adjusting, or servicing orthoses and prostheses by a licensed orthotist-prosthetist;

nor is an authorized health care practitioner's order required for maintenance of an orthosis or prosthesis to the level of its original prescription for an indefinite period of time if the order remains appropriate for the patient's medical needs. However, an orthotist-prosthetist may only provide treatment utilizing new orthoses-prostheses for which the orthotist-prosthetist is licensed to do so and only under an order from or referral by an authorized health care practitioner.

NEW SECTION. **Sec. 4.** (1) Orthotists-prosthetists must refer persons under their care to authorized health care practitioners if they have reasonable cause to believe symptoms or conditions are present that require services beyond the scope of their practice or for which the prescribed orthotic-prosthetic treatment is contraindicated.

(2) A violation of this section is unprofessional conduct under this chapter and chapter 18.130 RCW.

NEW SECTION. **Sec. 5.** No person may practice or represent himself or herself as either an orthotist or prosthetist, or both, without a valid license.

NEW SECTION. **Sec. 6.** This chapter does not prevent or restrict the practice, services, or activities of:

(1) A person licensed in this state under any law from engaging in a profession or occupation for which the person is licensed;

(2) A person directly employed as an orthotist-prosthetist or orthotic-prosthetic assistant by the government of the United States, if the person provides either orthotic or prosthetic care, or both, solely under the direction or control of the organization by which the person is directly employed;

(3) A person pursuing a course of study leading to a degree or certificate in orthotics-prosthetics in an accredited or approved educational program if the activities and services constitute a part of a supervised course of study, if the person is designated by a title that clearly indicates the person's status as a student or trainee;

(4) A person fulfilling the supervised residency or internship experience requirements described in section 13 of this act, if the activities and services constitute a part of the experience necessary to meet the requirements of this chapter;

(5) A person performing orthotic-prosthetic services in this state if the services are performed for no more than ninety working days and if:

(a) The person is licensed under the laws of another state that has licensure requirements at least as stringent as the requirements of this chapter, as determined by the advisory committee; or

(b) The person has met commonly accepted standards for the practice of orthotics-prosthetics as specifically defined by the advisory committee;

(6) A person employed by or supervised by an orthotist-prosthetist as an orthotic-prosthetic assistant;

(7) A person with a limited permit. A limited permit may be granted to a person who has completed the educational and experience requirements of this chapter, or educational and experience requirements that the advisory committee deems equivalent to those specified as requirements for licensure. The limited permit allows the applicant to practice in association with an orthotist-prosthetist. The limited permit is valid until the results of the next examination have been made public. One extension of this permit may be granted if the applicant has failed the examination, but during this period the person must be under the direct supervision of an orthotist-prosthetist;

(8) A person who provides services that include designing, fabricating, or applying temporary orthoses designed strictly for short-term, temporary use or evaluation purposes, or a person providing the following assistive technology devices: Commercially available knee orthoses for use following injury or surgery; spastic muscle tone-inhibiting orthoses; face masks used following burns; upper extremity adaptive equipment; finger splints; hand splints; wheelchair seating that is an integral part of the wheelchair and not worn by the patient; fabric or elastic supports; corsets; arch supports; low temperature-formed plastic splints; trusses; elastic hose; canes; crutches; cervical collars; dental appliances; or other similar devices commonly carried in stock by a pharmacy, department store, corset shop, or surgical supply facility;

(9) A person providing, designing, fabricating, or applying temporary, nonalignable, nonarticulated, or nonweightbearing prostheses;

(10) A person providing, designing, fabricating, or applying temporary, nonalignable, or nonarticulated prostheses including upper limb prostheses intended to restore function for amputations distal to and including the carpals; or

(11) A person providing, designing, fabricating, or applying weightbearing lower limb prostheses for amputations distal to and including the transmetatarsal level.

NEW SECTION. **Sec. 7.** (1) There is established an orthotics and prosthetics advisory committee. The advisory committee consists of five members appointed by the governor. The governor may consider the persons who are recommended for appointment by the orthotic and prosthetic associations of the state. The members of the advisory committee must be residents of the state. Three of the members must have been engaged in rendering services to the public. One member must be a practicing orthotist. One member must be a practicing prosthetist. Two members must be members of the public, including consumers of orthotic and prosthetic professional services. One member must be licensed by the state as a doctor of medicine or doctor of osteopathy, specializing in orthopedic medicine or surgery or a podiatric physician or surgeon. Two of these five members must at all times be holders of licenses for the practice of either prosthetics or orthotics, or both, in this state, except for the initial members of the advisory committee, all of whom must fulfill the requirements for licensure under this chapter.

(2) The governor must, within sixty days after the effective date of this act, appoint one member for a term of one year, two members for a term of two years, and two members for a term of three years. Appointments made thereafter are for three-year terms, but no person may be appointed to serve more than two consecutive full terms. A term begins on the first day of the calendar year and ends on the last day of the calendar year or until a successor is appointed, except for the initial appointed members, who serve through the last calendar day of the year in which they are appointed before commencing the terms prescribed by this section. The governor must make an appointment for a vacancy in an unexpired term within ninety days after the vacancy occurred.

(3) The advisory committee must meet each January to select a chair and for other purposes. At least one additional meeting must be held

before the end of each calendar year. Further meetings may be convened at the call of the chair or upon the written request of two advisory committee members. A majority of the members of the advisory committee constitutes a quorum for all purposes. All meetings of the advisory committee are open to the public, except that the advisory committee may hold closed sessions to prepare, approve, grade, or administer examinations, or, upon request of an applicant who fails an examination, to prepare a response indicating the reasons for the applicant's failure.

(4) Members of the advisory committee are compensated in the amount of fifty dollars for each day's attendance at proper meetings of the committee.

(5) A member may be removed from the advisory committee by the governor for:

(a) Loss of license as an orthotist, prosthetist, or orthotist-prosthetist;

(b) Loss of license as a doctor of medicine, doctor of osteopathy, or podiatric physician or surgeon;

(c) Failure to fulfill his or her duties and responsibilities as an advisory committee member; or

(d) Having been found to be culpable for committing acts of moral turpitude, malfeasance in office, or criminal behavior.

NEW SECTION. **Sec. 8.** (1) The secretary must prescribe and publish fees in amounts determined by the secretary as provided in RCW 43.70.110 for the following purposes:

(a) Application for examination;

(b) Initial license fee;

(c) Renewal of license fee;

(d) Late renewal fee; and

(e) Limited permit fee.

(2) The fees must be set in such an amount as to reimburse the state, to the extent feasible, for the cost of the services rendered.

NEW SECTION. **Sec. 9.** (1) The advisory committee administers, coordinates, and enforces this chapter, evaluates qualifications under this chapter, and provides for supervision of examinations of applicants for licensure under this chapter.

(2) The advisory committee is responsible for the licensure of orthotists, prosthetists, and orthotists-prosthetists, orthotic or prosthetic assistants, and persons eligible to be licensed in the disciplines of either orthotics or prosthetics, or both, as licensed orthotists, prosthetists, orthotists-prosthetists, or assistants.

(3) The advisory committee must review applications for licenses at least once a year. The advisory committee may collect license application fees, renewal fees, examination fees, and other administrative fees. The advisory committee must set the fees in amounts reasonable and necessary to carry out the program.

(4) The advisory committee must approve an examination required for a license under this chapter.

(5) The advisory committee may:

(a) Investigate complaints;

(b) Issue, renew, suspend, deny, and revoke licenses;

(c) Reprimand license holders and place them on probation;

(d) Issue subpoenas;

(e) Hold hearings;

(f) Delegate authority for all or a portion of the activities in (a) through (e) of this subsection to a qualified contractor; and

(g) Determine fines.

(6) The advisory committee must maintain an information file about each complaint filed with the advisory committee. The advisory committee must also notify parties to the complaint quarterly as the status of the complaint unless this action would jeopardize an ongoing investigation.

(7) The advisory committee must assist legal authorities in the prosecution of a person violating this chapter.

(8) The advisory committee must prepare or approve continuing education programs for license holders and adopt rules requiring license holders to participate in the programs as a condition of renewing a license under this chapter.

(9) The advisory committee may make arrangements to accept practitioners who have been duly licensed by another state without further examination.

(10) The advisory committee may adopt rules as it deems necessary in the administration of this chapter.

NEW SECTION. **Sec. 10.** The secretary must provide administrative and investigative staff as are necessary for the advisory committee to carry out its duties under this chapter.

NEW SECTION. **Sec. 11.** The two members appointed to the advisory committee representing the public at large must have an interest in the rights of consumers of health services, and must not be or have been a member of another licensing committee, a licensee of a health occupation committee, an employee of a health facility, nor derive his or her primary livelihood from the provision of health services at any level of responsibility.

NEW SECTION. **Sec. 12.** The advisory committee may adopt rules in accordance with the administrative procedure act, chapter 34.05 RCW, relating to standards for appropriateness of orthotic-prosthetic care. A violation of the standards adopted by rule under this section is unprofessional conduct under this chapter and chapter 18.130 RCW.

NEW SECTION. **Sec. 13.** (1) An applicant applying for a license as an orthotist-prosthetist or as an orthotic-prosthetic assistant must file a written application on forms provided by the department showing to the satisfaction of the advisory committee that the applicant meets the following requirements:

(a) The applicant is of good moral character;

(b) The applicant possesses a baccalaureate degree from an accredited college or university;

(c) The applicant has the amount of formal training, including the hours of classroom education and clinical practice, in areas of study as the advisory committee deems necessary and appropriate;

(d) The applicant has completed a clinical internship or residency in the professional area for which a license is sought in accordance with the standards, guidelines, or procedures for clinical internships or residencies inside or outside the state established by the advisory committee; and

(e) An applicant for licensure as either an orthotist or prosthetist, or both, must:

(i) Pass all written, practical, and oral examinations that are required and approved by the advisory committee; or

(ii) Be qualified to practice in accordance with the American board for certification in orthotics and prosthetics.

(2) The standards and requirements for licensure established by the advisory committee must be substantially equal to or in excess of standards commonly accepted in the fields of orthotics and prosthetics.

(3) The advisory committee may adopt rules in accordance with the administrative procedure act, chapter 34.05 RCW, that are necessary to effectuate the requirements of this section.

(4) The advisory committee may waive the educational requirements specified under subsection (1)(b) of this section for an orthotic-prosthetic assistant who has met the experience and other requirements established by the advisory committee. Upon successful completion of the examination required of either the orthotist or the prosthetist, or both, the individual must be granted a license for that discipline.

NEW SECTION. **Sec. 14.** (1) A person applying for licensure must demonstrate eligibility in accordance with section 13 of this act and must apply for the examination upon a form and in a manner as the department prescribes. The application must be accompanied by the fee prescribed. The fee is nonrefundable. A person who fails an examination may apply for reexamination. The reapplication must be accompanied by the prescribed fee.

(2) An applicant for licensure under this chapter must be given a written examination to test the applicant's knowledge of the basic and clinical sciences relating to orthotics-prosthetics and orthotics-prosthetics theory and practice including the applicant's professional skills of orthotic-prosthetic techniques and methods, and other subjects as the advisory committee deems useful to determine the applicant's fitness to practice. The advisory committee approves the examination and establishes standards for acceptable performance.

(3) Applicants for licensure must be examined at a time and place and under such supervision as the advisory committee may determine. The examination must be given at least once each year at those places as the advisory committee determines, and the advisory committee must give reasonable public notice of the examinations in accordance with its rules at least sixty days prior to the administration of the examination.

(4) Applicants may obtain their examination scores and may review their papers in accordance with rules established by the advisory committee.

NEW SECTION. **Sec. 15.** (1) The advisory committee may waive the examination and grant a license to a person engaged in the profession of either an orthotist or prosthetist, or both, or either an orthotic or prosthetic assistant, or both, if the advisory committee determines that the person meets commonly accepted standards for the profession, as established by rule by the advisory committee. The advisory committee may waive the examination, education, or experience requirements and grant a license to a person meeting the standards adopted by the advisory committee under this section, if the advisory committee determines that the requirements for licensure in this chapter have been met.

(2) The advisory committee may grant a license to an applicant who presents proof of current licensure as either an orthotist or prosthetist, or both, or either an orthotic or prosthetic assistant, or both, in another state, the District of Columbia, or a territory of the United States, that requires standards for licensure considered by the advisory committee to be equivalent to the requirements for licensure under this chapter.

(3) The advisory committee must waive the education and experience requirements for licensure under section 13(1)(c) and (d) of this act for applicants for licensure who present evidence to the advisory committee that they have practiced full time for the past five years and have provided comprehensive orthotic-prosthetic, or orthotic and prosthetic care in an established orthotic and prosthetic facility for the five years immediately prior to the effective date of this act. The application must be filed with the advisory committee within one hundred eighty days of the effective date of this act in order to continue to practice either orthotics or prosthetics, or both, under the provisions of this chapter without taking an examination as required under this chapter. The applicant must pay all licensing fees required under this chapter. The advisory committee must complete an investigation into the applicant's work history. The investigation may include, but is not limited to, completion by the applicant of a questionnaire regarding his or her work history and scope of practice.

(4) For the purposes of this section, the advisory committee must complete its investigation of the applicant within one hundred eighty days of the date of the application.

NEW SECTION. **Sec. 16.** The secretary must issue a license to a person who meets the licensing requirements of this chapter upon payment of the prescribed license fee. The license must be posted in a conspicuous location at the person's work site.

NEW SECTION. **Sec. 17.** The secretary must furnish a license upon the authority of the advisory committee to a person who applies and is qualified under the provisions of this chapter. At the time of application the applicant must pay to the state treasurer a fee determined by the secretary as provided under section 8 of this act.

NEW SECTION. **Sec. 18.** (1) Licenses under this chapter must be renewed at the time and in the manner determined by the secretary and with the payment of a renewal fee. The advisory committee must establish requirements for license renewal that provide evidence of continued competency. The secretary may provide for the late renewal of a license upon the payment of a late fee, additional continuing education or examination requirements, or other requirements as determined by the advisory committee by rule.

(2) A suspended license is subject to expiration and may be renewed as provided in this section, but the renewal does not entitle the licensee, while the license remains suspended and until it is reinstated, to engage in the licensed activity, or in other conduct or activity in violation of the order or judgment by which the license was suspended. If a license that was revoked on disciplinary grounds is reinstated, the licensee, as a condition of reinstatement, must pay the renewal fee and an applicable late fee.

(3) Either an orthotist or a prosthetist, or both, and orthotic or prosthetic assistant, or both, licensed under this chapter not practicing orthotics-prosthetics or providing services may place his or her license on an inactive status. The secretary may set by rule requirements for maintaining an inactive status and converting from an inactive or active status.

NEW SECTION. **Sec. 19.** A person who is not licensed with the secretary as either an orthotist or a prosthetist, or both, under the requirements of this chapter must not represent him or herself as being so licensed and may not use in connection with his or her name the words or letters "L.O.," "L.P.," or "L.P.O.," or other letters, words, signs, numbers, or insignia indicating or implying that he or she is either an orthotist or a prosthetist, or both. No person may practice orthotics-prosthetics without first having a valid license. Nothing in this chapter prohibits a person licensed in this state under another law from engaging in the practice for which he or she is licensed. It is the duty of the prosecuting attorney of each county to prosecute all cases involving a violation of this chapter arising within his or her county. The attorney general may assist in the prosecution and must appear at all hearings when requested to do so by the advisory committee.

NEW SECTION. **Sec. 20.** If a person violates the provisions of this chapter, the attorney general, the prosecuting attorney, the secretary, the advisory committee, or a citizen of the same county, may maintain an action in the name of the state to enjoin a person from practicing or holding himself or herself out as practicing orthotics-prosthetics. The injunction does not relieve criminal prosecution but the remedy by injunction is in addition to the liability of the offender for criminal prosecution and the suspension or revocation of his or her license.

NEW SECTION. **Sec. 21.** The secretary must keep a record of proceedings under this chapter and a register of all persons licensed under it. The register must show the name of every living licensed orthotist or prosthetist, and his or her last known license as an orthotist or prosthetist.

NEW SECTION. **Sec. 22.** This chapter is known and may be cited as the orthotics-prosthetics practice act.

NEW SECTION. **Sec. 23.** The uniform disciplinary act, chapter 18.130 RCW, governs unlicensed practice, the issuance and denial of licenses, and the discipline of licensees under this chapter.

NEW SECTION. **Sec. 24.** Sections 2 through 23 of this act shall constitute a new chapter in Title 18 RCW.

NEW SECTION. **Sec. 25.** If any provision of this act or its application to any person or circumstance is held invalid, the remainder of the act or the application of the provision to other persons or circumstances is not affected.

NEW SECTION. **Sec. 26.** This act is necessary for the immediate preservation of the public peace, health, or safety, or support of the state government and its existing public institutions, and shall take effect immediately.

--- END ---

APPENDIX B

APPLICANT CHECKLIST

APPLICANT CHECKLIST

Washington State Department of Health
SUNRISE REVIEW

1. Legislative proposal being considered:
   Orthotic and Prosthetic Licensure in Washington State
   Reference # H-0010.1/97

2. Applicant's organization:
   Washington Orthotic and Prosthetic Association
   411 Twelfth Avenue
   Seattle, WA 98122-5599

   Contact: David Varnau, CPO
   (206)328-4276
   (206)328-1037 Fax

3. Number of members in organization:
   34 members, 22 practices

   Number of individuals practicing in Washington State:
   81 practitioners certified at the national level (ABC)
   8 practitioners BOC certified

4. Name/Address of national organization:
   American Orthotic and Prosthetic Association
   1650 King Street, Suite 500
   Alexandria, Virginia 22314

   Name of other state organizations representing profession
   Washington Orthotic and Prosthetic Association

5. Name and title of profession seeking to credential:
   Prosthetists, Orthotists

List and describe major functions and procedures performed by members of the profession:

Space limits listing the scope of practice.

Prosthetists Apply knowledge of biomechanics, anatomy, kinesiology and physics to mobilize patients with replacement of a limb(s)

Orthotists Apply similar fields of knowledge to support, correct, replace function of a diseased, injured or malaligned body segment.

6. Training and Education:

Prosthetists and Orthotists typically follow The Pathway to Competency. Either a post graduate certificate program is completed, or a Bachelor of Science is obtained in prosthetics and orthotics. Both routes are followed by a residency program of 1800 hours in each field under the direct supervision of a Certified Practitioner prior to eligibility to sit for the national board exams.

7. Titles of other health care providers performing related services:

BOC (Board for Orthotic Certification) Training: 5 day course followed by two years of supervision under BOC certifee. BOC certificate exam.

NARD (National Association of Retail Druggists)
Physical Therapists
Occupational Therapists
Pediatrists
Pedorthotists
Orthotic fitters*

*Attended 4-5 day supplier course in fitting certain pre-fabricated orthoses. There are 18 individuals in Washington State who have attended these courses and hold title of "orthotic fitter".

This bill does not seek to restrict the ability of an individual to continue fitting devices for which they are qualified to do. The ability to design, fit and fabricate prostheses and orthoses intended for long term use, requiring knowledge to do so safely, can only be assured by those individuals who can demonstrate the training and competency to provide these services.